Effectiveness of a training intervention to improve the management of vertigo in primary care: a multicentre cluster-randomized trial.

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Abstract

Background

Benign paroxysmal positional vertigo (BPPV) is the most common type of vertigo. While BPPV is best treated with canalicular repositioning maneuvers, they are not routinely performed in primary care (PC).

Methodology

Objectives:

To evaluate the effectiveness of blended training (online and face-to-face) on the diagnosis and management of vertigo to improve adherence of family doctors to clinical practice guidelines.

Design

Community multicenters cluster-randomized open-label trial with an intervention (IG) and a control group (GC) of 10 primary care teams (PCTs) each.

Measurements

Outcome variables will be: ICD-10 diagnostic codes (proportion of nonspecific diagnoses such as dizziness and vertigo versus specific diagnoses such as BPPV, vestibular neuritis and Meniere's syndrome); referrals to ENT and neurology specialists; prescription of antivertigo agents; duration of sick leave due to vertigo.

Statistical analysis

The baseline comparability of the two study groups will be analysed to ensure homogeneity. A description of all baseline variables will be performed. Student’s t-test will be used to evaluate differences between groups. Logistic regression multivariate analysis will be performed to study the relationship between baseline variables of professionals and centers with outcome variables.

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Ethics

This protocol has been approved by the Ethics Committee of the Institut Universitari d’Investigació en Atenció Primària Jordi Gol (IDIAP Jordi Gol) with the code 20/004-P. All patient data will be anonymised in agreement with the 2016/679 European Regulation.

Expected results and Applicability

With the improvement of the diagnosis and management of vertigo by family doctors after this training we expect: an increase in the proportion of specific diagnoses; a decrease in the prescription of antivertigo agents; a decrease in the request for complementary tests and referrals to other specialists; a reduction in the duration of sick leave due to temporary disability. The blended training will be easily expanded within primary care services, since it is mainly delivered online, with a single face-to-face session to ensure that the maneuvers have been adequately learned.

Introduction

Background and rationale

Dizziness affects 20-30 % of people at some point in their lives [1]. Approximately 5% of primary care consultations are due to dizziness, and over 50% of patients with dizziness are firstly assessed by family doctors [2, 3].

Vertigo, defined as the sensation of spinning objects and instability, severely affects the quality of life, causes a twofold increase in the prevalence of functional disability, worsens symptoms of depression [4] and decreases participation in social activities and self-efficacy to prevent falls [5]. A total 69.8% patients with vertigo have to reduce their work activities and 63.3% need to take sick leave for several days [6]. Vertigo is associated with high costs for the health services [6].

Benign paroxysmal positional vertigo (BPPV) is the most common cause of peripheral vertigo, affecting between 17% and 42% patients with vertigo [7]. Up to 85-95% cases of BPPV affect the posterior canal (BPPV-PC), and the Dix-Hallpike test (DHT) is considered the gold standard for its diagnosis[7]. As shown in literature reviews **[8,9,10,11]** the Epley maneuvers (EM) is the most effective for treating BPPV-PC **[12]**. Consequently, with the use of the DHT and the EM, patients can be quickly identified and treated during primary care consultations without need for referral or expensive medical tests. Clinical practice guidelines recommend the DHT and the EM, advise against the use of medical tests (except in the few cases where the diagnosis is unclear), and against the use of antivertigo agents [7].

Despite these recommendations, 60 to 80% patients are visited in PC and hospital emergency departments where these diagnostic and treatment tests are not routinely performed [13,14,15]. A study by Dunlap PM et al. (2019) based on 20.6 million PC visits (95% CI: 17.3, 24.0) for dizziness observed a low percentage of treatments such as repositioning maneuvers and a frequent diagnosis of “nonspecific dizziness” (75%).

Three main reasons were given for not implementing these diagnostic and therapeutic procedures (especially DHT and EM) in primary care: (1) the evidence originates from studies conducted in clinics with specialists (2) with easy access to instruments that facilitate the visualization of nystagmus during the DHT and (3) the lack of training on how to perform these maneuvers [16].

To improve this situation, a German protocol of a cluster-randomized trial was published in 2018 to evaluate the benefits of a half-day training for GPs [17]. A similar study protocol for ER physicians was published in the United States in the same year[18]. This latest study has reported twice as much DHT and ME in the intervention group than in the control, in a 2020 publication [19].

Our group has recently published a clinical trial [20] in patients with BPPV-PC that compared the performance of a single EM with the simulated maneuvers performed by family physicians who had participated in a 2-hour training workshop. This trial demonstrated that after receiving brief training, GPs can effectively diagnose and treat patients with BPPV-PC. However, the real challenge is to integrate these diagnostic and treatment maneuvers into the everyday practice of all primary care physicians.

The objective of this study is to assess if a training intervention for GPs can optimize the diagnosis and management of patients with vertigo.

Objectives

Hypothesis

Better training on the diagnosis and treatment of vertigo and BPPV will improve the adherence of professionals to the vertigo clinical practice guidelines.

General Objective

To evaluate the effectiveness of a blended training intervention (online and face-to-face) regarding adherence to the BPPV clinical practice guidelines for the diagnosis and management of vertigo in PC.

Specific objectives

- Assess if the diagnostic codes of vertigo in the PC teams (PCT) that have received the training (Intervention Group (IG)) have improved compared to PCT in the Control Group (CG): decrease of nonspecific diagnoses such as dizziness and vertigo and increase in specific diagnoses such as BPPV, vestibular neuritis, vestibular migraine and Meniere's disease (see Supplementary material 1 for the complete list of diagnoses considered specific and nonspecific)
- Assess if referrals to ear nose throat (ENT) and neurology specialists due to vertigo are lower in the IG compared to the CG.
- Assess if there is a decrease in the prescription of antivertigo agents in the IG compared to the CG.
- Assess if the sick leave duration (in days) in the IG is shorter than in the CG.

Trial design

To measure the effectiveness of the training in the IG, we designed a community multicenter cluster-randomized open-label trial, with the PCT as allocation unit. The professionals of the PCT in the IG will receive the training at the beginning of the study. PCT in the CG will be offered the training after study

completion. Adherence to clinical practice guidelines will be measured during the year after completion of training in each PCT.

Methods: Participants, Interventions And Outcomes (Fig. 1)

Setting:

Costa de Ponent Primary Care Management (Area Metropolitana Sud – Catalan Institute of Health), which in 2016 had 53 PCTs for a catchment population of 1,334,381 people, of which 1,042,920 had been visited during that same year. A random sample of 20 PCT will be chosen from the 53; 10 will be included in the IG, and 10 in the CG.

Study population:

Family physicians (GPs) working in the selected PCT in the Area Metropolitana Sud of the ICS.

Study period: pre-intervention study period from October to December 2021 and post-intervention period from January to December 2022.

Eligibility criteria

Inclusion Criteria:

- Patients assigned to the 20 randomized primary care teams out of the 56 that make up the "Costa de Ponent" Primary Care Department that serve a population of 1.3 million people, having any of the specific or unspecific diagnoses related to vertigo

Exclusion Criteria:

- Primary care teams in which> 60% of their professionals have received a course on vertigo in the last 5 years will be excluded.
- Primary care teams who are not interested in participating in the study will be excluded.
- Patients who die during the year before and after the training intervention.
- Displaced patients.

Interventions

Explanation for the choice of comparators

Active Comparator: Training group

The professionals of the primary care teams that are in Intervention group would receive the training at the beginning of the study

Other: Training on vertigo

Online training on vertigo management in primary care with a face-to-face session.

On the one hand, the course will contain theoretical content and clinical cases will be used as the methodology of the course, with feedback paths for each correct or incorrect answer from the students and videos recorded expressly for the course. In addition, there will be a face-to-face session where all participants must perform the diagnostic and therapeutic maneuvers proposed in the course, to evaluate the use of the training and also to standardize the way of doing them for the study

No Intervention: Common Practice

The professionals of the primary care teams that are in Control group will be offered the training after the conclusion of the study

Intervention description

We will design a virtual course for GPs with interactive clinical cases to improve the diagnosis and treatment of patients with vertigo. Support material will include videos explaining the main diagnostic and therapeutic maneuvers. Finally, we will review and practice the maneuvers in a face-to-face session. In this session we will also standardize the diagnosis and management of vertigo. The IG will complete the course before and the CG after the study period. The IG and CG will receive an information session about the study, where the informed consent of all professionals interested in participating will be requested.

Outcomes

Data from the whole population assigned to participating PCT will be obtained from the Information System for the Development of Research in PC (SIDIAP) before starting the training and during a year thereafter.

Exposure variable:

Allocation to the intervention and control groups (IG / CG).

Primary Outcome Measures:

Dependent variables:

- Register of ICD-10 vertigo diagnoses:
    - Specific diagnoses registered during the study: BPPV (H81.1), Meniere's vertigo (H81) and vestibular neuritis (H81.2).

- Unspecific diagnoses registered during the study: dizziness or vertigo (R42) and other peripheral vertigos (H81.3).
- Ratio of specific diagnoses: ratio of specific versus nonspecific diagnoses. Effectiveness: higher proportion of specific diagnoses and lower of nonspecific diagnoses in the IG compared to the CG (see Supplementary material 1 for the complete list of diagnoses considered specific and nonspecific).

• Percentage of patients treated with antivertigo agents (betahistine, sulpiride, dimenhydrinate) in relation to all patients with vertigo in the PCT. Effectiveness: lower proportion of antivertigo prescriptions in the IG compared to the CG.

• Percentage of referrals to neurology and / or ENT due to vertigo (H81.1, H81.1, H81.3 and R42). Effectiveness: lower proportion of referrals in the IG compared to the CG.

• Total number of sick leave days due to vertigo in the IG. Effectiveness: less sick leave days in the IG compared to the CG.

Independent variables:

• Characteristic of the PCT: teaching center yes / no, number of tutors, rural / urban.

• Characteristics of physicians: age, sex, years of professional practice, tutor yes / no.

Study flowchart Fig. 1

Participant timeline

Work plan and chronogram. (Fig. 2)

PHASE 1. Preparatory: Meeting of all the researchers to agree on the work protocol and the manual of procedures. Planning of the distance learning course. Contact with the company that will provide technical support and elaborate the course materials. Recording of the videos with all the diagnostic and therapeutic maneuvers with simulated patients.

This phase will start in November 2019 and will last until March 2021. Meetings of the whole research team with the specialist in Otorhinolaryngology (Dr. Xavier Gonzalez Compte) who is supervising the results will be held.

We will contact SIDIAP to help us to randomize the participating centers among the EAPs of Costa de Ponent as well as to help us to define well the variables of the study.

PHASE 2. Presentation and offer of the study to 20 EAPs in the area (DAP Costa de Ponent): Those that accept to participate will be randomly assigned to the GI or GC.

The EAPs that are part of the IG will be offered the course at the beginning of the study and those of the CG, once the follow-up period of the study is over.

The study presentation visits will take place in the second quarter of 2021. Time will be given to the researchers during the summer and until October 2021 to carry out the course and the face-to-face sessions will be held in October-December 2021.

PHASE 3. Period of information collection will be extended during January 2022-Dec 2023.

PHASE 4. Analysis of results: All data will be passed to a statistical technician for analysis. All the researchers will meet on one or several occasions to analyze with the technician all the possible analyses to be made as well as their best interpretation. The final report of the study will be written with the consent of all the researchers. This phase will begin in January 2024 and will last until March 2024.

Dissemination of the results in national and international congresses and publication of

the results in journals of impact. All this during the year 2024.

Sample size

Population sample:

To improve vertigo diagnostic codes, accepting an alpha risk of 0.05 and a beta risk < 0.2 in a two-sided test, a total of 356 patients are needed per each group (IG and CG) to detect as statistically significant a difference of 30% and 40% in correct diagnoses (BPPV, vestibular neuritis, vestibular migraine and Menière's disease) for the CG and IG, respectively, with no loss to follow up anticipated (GRANMO calculator, Institut Municipal d 'Investigation Médica, Barcelona, Spain, using the ARCSINUS approach). To evaluate the final sample size, we take into account that the Intercluster Correlation Coefficient (ICC) most commonly used in cluster-randomized trials in PC is 0.05. This ICC translated to a size of 45 individuals (assuming 10 clusters per group) in the design is adjusted by 1.24, i.e., n = 712 * 1.24 = 884 (45 per center).

Similarly, the comparison of expected variation proportions for the prescription of antivertigo agents is 58.21% and 48% for the CG and IG, respectively (374 per group before adjustment by design) and 20% and 10% for referrals to neurology and ENT (195 per group before adjustment for design). All proportion estimates are based on the results of the previously published study19.

However, data from *all* patients with a new diagnosis of vertigo and dizziness during the study period (one year after the intervention) in participating centers will be collected, ensuring a number greater than the sample calculation.

Recruitment

Recruitment will be carried out in the Primary Care Management Costa de Ponent corresponding to the Southern Metropolitan Area of the Catalan Institute of Health, which in 2016 had 53 PCTs for a catchment population of 1,334,381 people, of whom 1,042,920 had been visited during that same year. A random sample of 20 PCTs will be chosen from the 53; 10 will be included in the IG and 10 in the CG.

Each primary health center will be personally visited to offer physicians the possibility of participating in the study.

Assignment of interventions: allocation

- We have taken all the 'Metropolitan Sud' centers.

- We have excluded centers that have taken BPPV courses and training.

- We have excluded the pediatric centers.

- From the remaining centers, we have used the random function to select 30 centers.

- We made a second random to classify them into two groups (control and intervention).

Confidentiality

The data will be collected by computerized exploitation without the need to look at other data in the medical record and will be coded in such a way that the patient cannot be identified.

Statistical methods

Data analyses will follow Consort Cluster recommendations (http://www.equator-network.org/reporting-guidelines/consort-cluster/)30 and intention-to-treat analysis will be used for comparisons between groups. We will firstly analyze the baseline comparability of the two groups to verify homogeneity regarding study variables. Descriptive statistics will be performed for all baseline variables, using Student’s t or Mann-Whitney U test for quantitative variables, and Chi-square or Fisher's exact test for categorical variables.

The t-test will evaluate differences in outcome variables between groups pre- and post-intervention. Logistic regression multivariate analysis will be performed to analyze the relationship between baseline variables of primary care centers and professionals and outcome variables. Significance will be set at 5% for all analyses. Statistical software R (revised version 3.2.4) will be used.

Oversight and monitoring

The management structure comprises the principal investigator (IP), the members of the VERTAP group (BPPV research group) and a collaborating center that will manage the data.

The members of the VERTAP group are the responsible for the conduct of the clinical trial and will divide the tasks to oversee day-to-day timely completion of the trial and will meet monthly to discuss the progress of the trial monthly to discuss the progress of the trial.

The IP will monitor with each meeting that the study objectives are being met in a timely manner.

The oversight committee consists of the investigators from the VERTAP group and they will periodically review the progress of the study.

The final analysis will be performed by the database research center and our statistician and our statistician. Additional follow-up may be performed at the discretion of the monitoring manager.

Data collected in this trial will include information recorded and encrypted in the database.

Dissemination plans {31a}

Dissemination of the results in national and international congresses and publication of the results in journals of impact. All this during the year 2024.

Discussion

The study aims to evaluate the effect of a management training activity to increase GP adherence to vertigo clinical practice guidelines and consequently increase the rate of specific diagnoses such as BPPV, vestibular neuritis and Menière disease. Specific diagnoses, particularly of BPPV, should be followed by specific treatments such as repositioning manoeuvres, a decrease in referrals to other specialties (mainly ENT and neurology) and a decrease in sick leave days. In addition to BPPV, the most common cause of vertigo, other common causes of peripheral vertigo such as vestibular migraine are also underdiagnosed [21]. Similarly, the head impulse test for the diagnosis of vestibular neuritis is not routinely performed in PC consultations [22]. As a result, even in ENT clinics patients with vertigo mostly receive nonspecific diagnoses such as “dizziness” (67%) or “Vestibular function disorder, unspecified”, and are prescribed ineffective antivertigo agents, especially in cases of BPPV [23].

Geser and Straumann found that the number of BPPV diagnoses doubled with subsequent specialist evaluation, and that nonspecific diagnoses decreased from 70 to 10% after a neuro-otological assessment, underscoring the need to improve neuro-otological skills among primary care physicians [24].

According to a comprehensive review on the economic burden of vertigo in Germany, 82% patients with vertigo underwent magnetic resonance imaging (MRI) or computerized axial tomography (TAC) before being visited by a specialist for vestibular problems. In contrast, the head impulse test and the DHR were only performed in 5% and 34% of cases, respectively. Similarly, the best evidence-based treatment (the Epley repositioning manoeuvre) was performed in only 15% of patients with BPPV, while vertigo patients were prescribed an average of 1.8 medications. The mean sick leave for patients with vertigo during a 12-month observation period was 69 days, with an estimated cost of USD 12,542.

In summary, we are faced with an underuse of inexpensive diagnostic tests that require specific training, and an overuse of mostly unnecessary, low diagnostic performance, expensive medical tests. Finally, medications that do not improve the condition and might even be contraindicated are excessively prescribed. In contrast, inexpensive and simple treatments that would result in a rapid improvement of many of these patients (especially patients with BPPV) but that require training of professionals are still largely underused [25].

Trial status:

The trial is recruiting participants. Recruitment has been ongoing from October 2021 until now and the completion date is scheduled for the end of January 2021.

Protocol version 1.0.

Figure 3 presents the VertAP trial logotype.

Abbreviations

-BPPV: Benign paroxysmal positional vertigo

-PC: Primary care

-GP: General Practitioner, Family Doctor

-CG: Control group

-IG: Intervention group

-ENT: Ear, nose and throat specialty

-BPPV- PC: Benign paroxysmal positional vertigo of the posterior canal

-DHT: Dix Hallpike Test

-EM: Epley Manoeuvre

-PCT: Primary Care Team

-ICS: Catalan Institute of Health

-TD: Temporary Disability

-ICC: Intercluster Correlation Coefficient

-SIDIAP: Information System for the Development of Research in Primary Care.

-IDIAP: Primary Care Research Institute

-LSSI: Information Society and Email Services

Declarations

Acknowledgments:

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Authors' contributions :

JEPP, JLBM, YRM, EPR, IVB, OLAA, RCM, VMR, ANC: conception, design and drafting, . data collection, analysis and interpretation of data, manuscript writing, critical revision and final approval of manuscript.: OCP: data collection and analysis, critical revision and final approval of manuscript. JAO: conception, design and drafting, analysis and interpretation of data, manuscript writing and final approval of manuscript. XGC: interpretation of data, critical revision. All authors have read and approved the final version of the manuscript.

This study is an investigation included in the PhD thesis of Jenniffer Elizabeth Pérez Patiño (University of Barcelona).

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Availability of data and materials

The dataset will be available in a public repository after the acceptance of the manuscripts.

Ethics approval and consent to participate

Approved by the Ethics Committee of the IDIAP Jordi Gol with the code 20/004-P of March 4, 2020.

Data confidentiality: all data will be encrypted. The study will meet the European Regulation 2016/679 of the European Parliament and Council of April 27, 2016 regarding personal data protection (RGPD) and the Spanish Law 34/02 of July 11, Services of the Information Society and Electronic Mail (LSSI). The study will also meet the IDIAP Jordi Gol Guidelines for Good Research Practices in Primary Care.

Competing interests:

The authors are members of the Vertigo Research Group in Primary Care of the Institut Universitari d'Investigació en Atenció Primària Jordi Gol (IDIAP Jordi Gol) and declare that they have no conflicts of interest.

Authors' information:

JEPP, JLBM, YRM, EVR, IVB, OLAA, RCM, VMR are General Practitioners; ANC is a physiotherapist; OCP is a statistician; and JAO is an Specialist in Preventative Medicine and Public Health.

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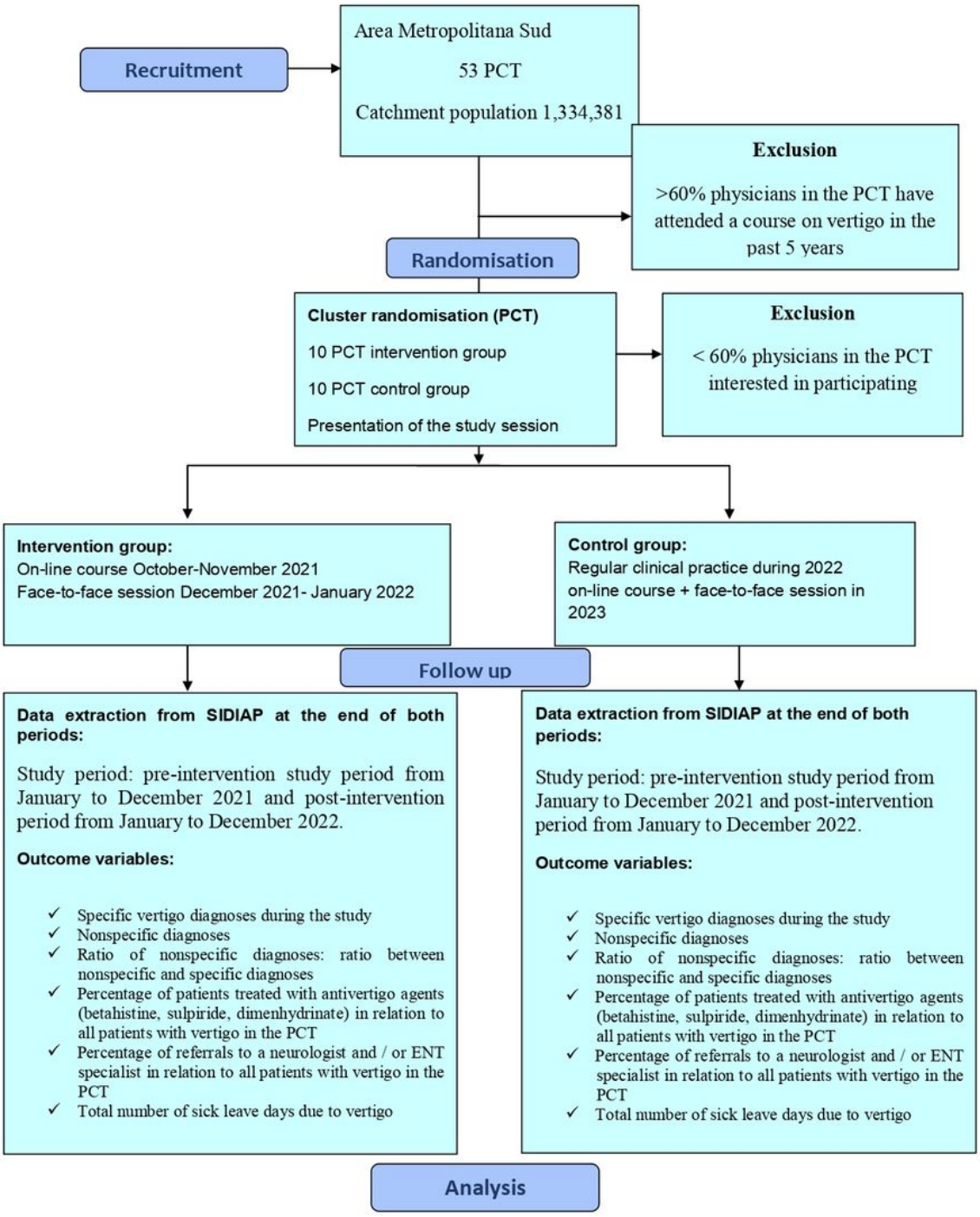
Figures



PCT: Primary Care Team; SIDIAP: Information System for Research in Primary Care;
ENT: Ear, nose and throat specialist

Figure 1

Study flowchart

Figure. 2 ; Schedule of enrolment, interventions, and assessments.*

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow ups
TIMEPOINT**	t_1		t_2	t_3	t_4	t_1 - t_4
ENROLMENT:	x					x
Eligibility screen	x					x
Presentation of thestudy			x			x
Allocation		x	x			x
INTERVENTIONS:			x			x
Online training			x			x
face-to-face session.			x	x		x
ASSESSMENTS:				x		x
Period of information collection				x	x	x
Analysis of results					x	x
Dissemination of theresults						x

**List specific timepoints : t1: Noviembre 2019 - March 2021 ; t2: April 2021-December 2021 ; t3: January 2022-Dec 2023; t4: January 2024 - December 2024

Figure 2

See image above for figure legend.

Fig. 3 VertAP trial logotype.

Figure 3

See image above for figure legend.

Supplementary Files

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- SPIRITFillablechecklist15Aug2013.doc
- DIAGNOSES.docx